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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/577,297	**Applicant(s)** SCHNITZLER ET AL.	
	Examiner RONALD HUPCZEY, JR	**Art Unit** 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _25 January 2011_.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1,3,6-9,12-15,17 and 19-22_ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1,3,6-9,12-15,17 and 19-22_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _04/27/2006_ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 25th, 2011 has been entered.

2. Applicant's amendments and remarks, filed January 25th, 2011, are acknowledged. Currently, claims 1, 3, 6-9, 12-15, 17 and 19-22 are pending with claims 1, 9 and 20 amended and claims 2, 4-5, 10-11, 16 and 18 cancelled and claim 22 newly added. The following is a complete response to the January 25th, 2011 communication.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 6-9, 12-13, 15, 17 and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishikawa et al (JP 2002-301088 A).

(**It is noted that the rejections below have been formulated with respect to the machine translation of the Detailed Description of JP 2002-301088 A which has been included with this communication for Applicant's reference. The various reference and paragraph numbers are taken from that document as well.**)

Regarding claims 1 and 22, Ishikawa discloses an apparatus for coagulating tissue (see at least figures 1-5) comprising an electrode capable of producing a high-frequency current (knife **13** connected to a source of energy as in paragraph [0012]), a gas-delivering device (probe **3** with insertion portion **9** formed of resin tube **15**) having an outlet (through hole **47**) and being capable of delivering an inert gas (from tube **6** with an inactive gas as disclosed in at least paragraph [0009]) from said outlet into a space defined between the electrode and said tissue (see figure 7 displaying the output gas), such that a plasma is produced between the electrode and the tissue when the high-frequency current is applied to the inert gas (see paragraph [0003] discussing ionizing inert gas, paragraph [0051] discussing sprinkling hemostasis and paragraph [0053] discussing forming plasma), wherein a distal end of the electrode projects out of said gas-delivering device (see figure 2 and 3 showing knife **11** extending out of the device). Ishikawa further discloses a guiding device (insulating part **12**) comprised of an electrically insulating material (see at least paragraph [0013] discussing the materials of construction of part **12**) and disposed at the distal end of the electrode (see figures 2 and 3), the guiding device being capable of directing and guiding the plasma such that the plasma is diverted in a predetermined direction (see figure 7 displaying the direction of the gas/plasma output from the through hole **47**) wherein a cross-section of at least a portion of the guiding device is at least a size or larger than the size of the outlet in order to divert the plasma the space substantially radially with respect to said

outlet of said gas-delivering device (as in figure 7, the plasma extends into the space radially outward with respect to the through hole **47** with the relative sizes of the part **12** in relation to the through-hole **47** as exhibited in figures 3 and 7 with the part **12** having a larger cross-section at its widest point than the widest portion of through-hole **47**) and wherein the electrode is configured such that it may be retracted and pushed forward with respect to the gas-delivering device (see at least paragraph [0026] discussing the movement of the electrode via movement of cap component **50** and its associated structure).

Regarding claim 3, Ishikawa discloses that the guiding device is comprised of a thermally stable material (see at least paragraph [0013] discussing the materials of construction of part **12**).

Regarding claim 6, Ishikawa discloses with respect to the embodiment in figure 15 that the guiding device (insulation part **12**) has a concave configuration on a side thereof that faces the outlet (the shape of the transition between projection **40** and the remainder of part **12** having a concave-like configuration facing towards the through hole **47**).

Regarding claim 7, Ishikawa discloses that the guiding device has a contour which prevents mechanical damage if said guiding device touches said tissue (see the rounded contour of part **12**).

Regarding claim 8, Ishikawa discloses that the electrode is capable of being moved relative to said outlet (see paragraph [0026] disclosing the movement/projection of the knife **11**) such that when said electrode is moved into a retracted position said guiding device closes said outlet in a substantially leakproof manner (see the relative diameter of part **12** in relation to through hole **47**, with respect to figure 15, paragraph [0047] discloses that the part **40** is greater in diameter than **47** thereby rendering **12** greater in diameter than **47** and with such a relation,

when knife **11** and part **12** are retracted, a seal would be formed between **12** and the through hole **47**).

Regarding claim 9, Ishikawa discloses an apparatus for argon-plasma coagulating tissue (see at least figures 1-5) comprising a gas-delivering device (probe **3** with insertion portion **9** formed of resin tube **15**), an electrode disposed substantially coaxially with the gas-delivering device and configured to generate a high-frequency current (knife **13** connected to a source of energy as in paragraph [0012]), wherein a distal end of the electrode projects outward through an outlet of the gas-delivering device (see figure 2 and 3 showing knife **11** extending out of the device). Ishikawa further discloses a guiding device (insulating part **12**) disposed at the distal end of the electrode, wherein the guiding device is configured for guiding an a plasma stream flowing through the gas-delivering device the plasma stream being produced when said high-frequency current is applied to an inert gas delivered by the gas-delivering device (from tube **6** with an inactive gas as disclosed in at least paragraph [0009] and see paragraph [0003] discussing ionizing inert gas, paragraph [0051] discussing sprinkling hemostasis and paragraph [0053] discussing forming plasma), wherein the guiding device is comprised of a material that is electrically insulating and thermally stable (see at least paragraph [0013] discussing the materials of construction of part **12**), wherein the guiding device is disposed in an axially symmetric manner around the distal end of the electrode (see figures 2 and 3 showing the disposition of **12** about knife **11**) and a cross-section of at least a portion of the guiding device is at least a size of the outlet of the gas-delivering device in order to divert the plasma stream into a surrounding space substantially radially with respect to the outlet of the gas delivering device (see figures 7 showing the radial expansion of the fluid from through hole **47** with respect to the through hole

47 with the relative sizes of the part **12** in relation to the through-hole **47** as exhibited in figures 3 and 7) and wherein the electrode is configured such that it may be retracted and pushed forward with respect to the gas-delivering device (see at least paragraph [0026] discussing the movement of the electrode via movement of cap component **50** and its associated structure).

Regarding claim 12, Ishikawa discloses that the guiding device is shaped such that damage to the tissue is prevented if the guiding device touches the tissue (see the rounded shape of part **12** in at least figures 2 and 3).

Regarding claim 13, Ishikawa discloses that the guiding device is spherical (see figures 2 and 3 showing the shape of part **12**).

Regarding claim 15, Ishikawa discloses with respect to the embodiment in figure 15 that the guiding device (insulation part **12**) has a concave configuration on a side thereof that faces the outlet (the shape of the transition between projection **40** and the remainder of part **12** having a concave-like configuration facing towards the through hole **47**) and a substantially hemispherical surface at a surface facing away from the outlet of the gas-delivering device (see shape of the remainder of the part **12** facing away from hole **47** in figure 15).

Regarding claim 17, Ishikawa discloses that the electrode is capable of being moved relative to said outlet (see paragraph [0026] disclosing the movement/projection of the knife **11**) such that when said electrode is moved into a retracted position said guiding device closes said outlet in a substantially leakproof manner (see the relative diameter of part **12** in relation to through hole **47**, with respect to figure 15, paragraph [0047] discloses that the part **40** is greater in diameter than **47** thereby rendering **12** greater in diameter than **47** and with such a relation, when knife **11** and part **12** are retracted, a seal would be formed between **12** and the through hole

47). In light of this above relationship, Ishikawa shows that when the electrode is in a fully retracted state, the guiding device is seated on the outlet of the gas-delivering device (placement of part **12** against hole **47**).

Regarding claim 19, Ishikawa discloses that the guiding device is comprised of a ceramic (see paragraph [0023]).

Regarding claim 20, Ishikawa discloses an argon plasma coagulating probe assembly (see at least figures 1-5) comprising a tube (probe **3** with insertion portion **9** formed of resin tube **15**), an electrode disposed substantially coaxially with the tube and configured to generate a high-frequency current (knife **13** connected to a source of energy as in paragraph [0012]), wherein a distal end of the electrode projects outward through an outlet of the tube (see figure 2 and 3 showing knife **11** extending out of the through-hole **47**). Ishikawa further discloses a guiding device disposed at the distal end of the electrode (insulating part **12**), wherein the guiding device is configured for guiding an inert gas stream delivered from said outlet of the tube (from through-hole **47** with an inactive gas as disclosed in at least paragraph [0009] and see paragraph [0003] discussing ionizing inert gas, paragraph [0051] discussing sprinkling hemostasis and paragraph [0053] discussing forming plasma), wherein a cross-section of at least a portion of the guiding device is at least a size of the outlet in order to divert the inert gas stream substantially radially with respect to the outlet of the gas-delivering device (see figures 7 showing the radial expansion of the fluid from through hole **47** with respect to the through hole **47** with the relative sizes of the part **12** in relation to the through-hole **47** as exhibited in figures 3 and 7), wherein the guiding device is comprised of an electrically insulating and thermally stable material (see at least paragraph [0023]) and is configured to have a concave configuration on a side thereof that

faces the outlet (with respect to the embodiment in figure 15 that the guiding device (insulation part **12**) has a concave configuration on a side thereof that faces the outlet due to the shape of the transition between projection **40** and the remainder of part **12** having a concave-like configuration facing towards the through hole **47**) and is further configured to prevent mechanical damage if the guiding device touches the tissue (see the rounded shape of part **12** in at least figures 2 and 3), and wherein said electrode is movable relative to said outlet (see paragraph [0026] disclosing the movement/projection of the knife **11**) such that when said electrode is moved into a retracted position said guiding device closes said outlet in a substantially leakproof manner (see the relative diameter of part **12** in relation to through hole **47**, with respect to figure 15, paragraph [0047] discloses that the part **40** is greater in diameter than **47** thereby rendering **12** greater in diameter than **47** and with such a relation, when knife **11** and part **12** are retracted, a seal would be formed between **12** and the through hole **47**).

Regarding claim 21, Ishikawa discloses that the guiding device has a rounded contour (see figures 2 and 3 showing the shape of part **12**).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 3, 6-9, 12-13, 15, 17 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosmescu et al (US Pat. No. 6,149,648) further in view of Ishikawa (JP 2002-301088 A).

Regarding claims 1 and 22, Cosmescu discloses an apparatus for coagulating tissue (as best seen in figures 5, 6A-6C and 7A-C) comprising an electrode capable of producing a high-frequency current (electrode **112**), a gas-delivering device (tube **152**) having an outlet (opening at **154**) and being capable of delivering an inert gas from said outlet into a space defined between said electrode and said tissue (see spaces defined in figures 5, 6A-6C and 7A-C), such that a plasma is produced between said electrode and said tissue when said high frequency current is applied to said inert gas (see at least col. 14; 1-46 discussing the formation of an "argon beam"), wherein a distal end of said electrode projects out of said gas-delivering device (electrodes **112** extending as in figure 5). Cosmescu further discloses that the electrode is configured to be

retracted and pushed forward with respect to the gas-delivering device (see col. 13; 27- col. 15; 5). Cosmescu fails to recite the specifics of the claimed guiding device. Ishikawa discloses a similar multi-purpose argon plasma device containing an electrode and gas-delivering device as prescribed by claim 1. Ishikawa further discloses a guiding device comprised of an electrically insulating material (insulation part **12**, see paragraph [0023]) disposed at said distal end of said electrode (disposed at the end of knife part **11**) wherein the guiding device is capable of guiding and directing plasma such that the plasma is diverted in a predetermined direction (see flow of emitting gas and plasma in figure 7), wherein a cross-section of at least a portion of the guiding device is at least a size or larger than the outlet in order to divert the plasma into the space substantially radially with respect to the outlet of the gas-delivering device (as in figure 7, the plasma extends into the space radially outward with respect to the through hole **47** with the relative sizes of the part **12** in relation to the through-hole **47** as exhibited in figures 3 and 7 with the part **12** having a larger cross-section at its widest point than the widest portion of through-hole **47**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the electrode (knife part **13**) containing the guiding device (insulation part **12**) of Ishikawa in combination with the device of Cosmescu in order to have a combined device which can effectively cut, coagulate and supply plasma to a target tissue site. Both Cosmescu and Ishikawa are concerned with the direct contact and cutting/coagulation of tissue by the electrode as well as providing an argon plasma enhanced effect to treat a target site. Ishikawa provides an improvement to the device of Cosmescu by supplying the guide element, which as disclosed by Ishikawa, prevents the sticking of the electrode at a target area thereby

reducing the unintentional bleeding (see paragraph [0007]) and ensures that plasma can still be created at that target site thereby allowing the continued treatment at the target site.

Regarding claim 3, Cosmescu fails to disclose any specifics regarding the guiding device. Ishikawa discloses that the guiding device is comprised of an electrically insulative and thermally stable material (see at least paragraph [0013] discussing the materials of construction of part **12**) such that the guiding device can be exposed to the increased temperatures at the treatment site. In light of the combination provided in claim 1 above, it would have been obvious to supply the guiding device of the material specified by Ishikawa to provide for the above mentioned advantages.

Regarding claim 6, Cosmescu fails to disclose any specifics regarding the guiding device. Ishikawa discloses with respect to the embodiment in figure 15 that the guiding device (insulation part **12**) has a concave configuration on a side thereof that faces the outlet (the shape of the transition between projection **40** and the remainder of part **12** having a concave-like configuration facing towards the through hole **47**). In light of the combination provided in claim 1 above, it would have been obvious that in supplying the guiding device of Ishikawa, that such a configuration would be provided to the device.

Regarding claim 7, Cosmescu fails to disclose any specifics regarding the guiding device. Ishikawa discloses that the guiding device has a contour which prevents mechanical damage if said guiding device touches said tissue (see the rounded contour of part **12**). In light of the combination provided in claim 1 above, it would have been obvious that in supplying the guiding device of Ishikawa, that such a configuration would be provided to the device.

Regarding claim 8, Cosmescu fails to disclose any specifics regarding the guiding device. Ishikawa discloses that the electrode is capable of being moved relative to said outlet (see paragraph [0026] disclosing the movement/projection of the knife **11**) such that when said electrode is moved into a retracted position said guiding device closes said outlet in a substantially leakproof manner. This relationship is Ishikawa is due to the relative diameter of part **12** in relation to through hole **47** as shown in figure 15. Additionally, paragraph [0047] discloses that the part **40** is greater in diameter than **47** thereby rendering **12** greater in diameter than **47** and with such a relation, when knife **11** and part **12** are retracted, a seal would be formed between **12** and the through hole **47**. In light of the combination provided in claim 1 above, it would have been obvious that in supplying the electrode and guiding device of Ishikawa, the combination would allow for a seal to be formed between the outlet and the guiding device when the electrode/guiding device are in a retracted position. It is noted that the limitation of "substantially leakproof" does not require a perfect seal to be formed by rather that a majority, in this instance an amount greater than 50% of the flow, to be stopped from exiting the outlet by the guiding device.

Regarding claim 21, Cosmescu fails to disclose any specifics regarding the guiding device. Ishikawa discloses that the guiding device has a rounded contour (see figures 2 and 3 showing the shape of part **12**). In light of the combination provided in claim 1 above, it would have been obvious that in supplying the guiding device of Ishikawa, that such a configuration would be provided to the device.

Regarding claim 9, Cosmescu disclose an apparatus for coagulating tissue (as best seen in figures 5, 6A-6C and 7A-7C) comprising a gas-delivering device (tube **152**), an electrode

disposed substantially coaxially with the gas-delivering device and configured to generate a high-frequency current (electrode **112** placed within the tube **152**) wherein a distal end of the electrode projects outward through an outlet of the gas-delivering device (see figures 5-6C) and a guiding device disposed at the distal end of the electrode (enlarged portion of each of the electrodes **112** and **406/436**) wherein the guiding device is configured for guiding an inert gas stream flowing through the gas-delivering device (enlarged portion of each of the electrodes would effect the direction of the flow of gas over the electrode). Cosmescu further discloses that the electrode is configured such that it may be retracted and pushed forward with respect to the gas-delivering device (see col. 13; 27- col. 15; 5) and that a plasma stream is formed by the device when inert gas is passed over the electrode **112**. Cosmescu fails to disclose the specifics of the guiding device. Ishikawa discloses a similar multi-purpose argon plasma device containing an electrode and a gas-delivering device as prescribed in claim 1. Ishikawa further discloses a guiding device disposed at the distal end of the electrode (disposed at the end of knife part **11**) and configured to guide a plasma stream flowing from the gas delivery device (out from through hole **47**) wherein the plasma stream is produced due to the passing of inert gas over the high-frequency-supplied electrode. Ishikawa further discloses that the guiding device is comprised of a material that is electrically insulating and thermally stable (see at least paragraph [0023] disclosing the materials of part **12**), that the guiding device is disposed in an axially symmetric manner around the distal end of the electrode (see figures 2 and 3 showing the disposition of **12** about knife **11**) and a cross-section of at least a portion of the guiding device is at least a size of the outlet of the gas-delivering device in order to divert the plasma stream into a surrounding space substantially radially with respect to the outlet of the gas delivering device (as in figure 7,

the plasma extends into the space radially outward with respect to the through hole **47** with the relative sizes of the part **12** in relation to the through-hole **47** as exhibited in figures 3 and 7 with the part **12** having a larger cross-section at its widest point than the widest portion of through-hole **47**) and that the electrode is configured such that it may be retracted and pushed forward with respect to the gas-delivering device (see at least paragraph [0026] discussing the movement of the electrode via movement of cap component **50** and its associated structure). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the electrode (knife part **13**) containing the guiding device (insulation part **12**) of Ishikawa in combination with the device of Cosmescu in order to have a combined device which can effectively cut, coagulate and supply plasma to a target tissue site. Both Cosmescu and Ishikawa are concerned with the direct contact and cutting/coagulation of tissue by the electrode as well as providing an argon plasma enhanced effect to treat a target site. Ishikawa provides an improvement to the device of Cosmescu by supplying the guide element, which as disclosed by Ishikawa, prevents the sticking of the electrode at a target area thereby reducing the unintentional bleeding (see paragraph [0007]) and ensures that plasma can still be created at that target site thereby allowing the continued treatment at the target site.

Regarding claim 12, Cosmescu fails to disclose any specifics regarding the guiding device. Ishikawa discloses that the guiding device is shaped such that mechanical damage is prevented if the guiding device touches said tissue (see the rounded contour of part **12**). In light of the combination provided in claim 1 above, it would have been obvious that in supplying the guiding device of Ishikawa, that such a configuration would be provided to the device.

Regarding claim 13, Cosmescu fails to disclose any specifics regarding the guiding device. Ishikawa discloses that the guiding device is spherical (see figures 2 and 3 showing the shape of part **12**). In light of the combination provided in claim 1 above, it would have been obvious that in supplying the guiding device of Ishikawa, that such a configuration would be provided to the device.

Regarding claim 15, Cosmescu fails to disclose any specifics regarding the guiding device. Ishikawa discloses with respect to the embodiment in figure 15 that the guiding device (insulation part **12**) has a concave configuration on a side thereof that faces the outlet (the shape of the transition between projection **40** and the remainder of part **12** having a concave-like configuration facing towards the through hole **47**) and a substantially hemispherical surface at a surface facing away from the outlet of the gas-delivering device (see shape of the remainder of the part **12** facing away from hole **47** in figure 15). In light of the combination provided in claim 1 above, it would have been obvious that in supplying the guiding device of Ishikawa, that such a configuration would be provided to the device.

Regarding claim 17, Cosmescu fails to disclose any specifics regarding the guiding device. Ishikawa discloses that the electrode is capable of being moved relative to said outlet (see paragraph [0026] disclosing the movement/projection of the knife **11**) such that when said electrode is moved into a retracted position said guiding device becomes seated against the outlet. This relationship is Ishikawa is due to the relative diameter of part **12** in relation to through hole **47** as shown in figure 15. Additionally, paragraph [0047] discloses that the part **40** is greater in diameter than **47** thereby rendering **12** greater in diameter than **47** and with such a relation, when knife **11** and part **12** are retracted, a seal would be formed between **12** and the

through hole **47**. In light of the combination provided in claim 1 above, it would have been obvious that in supplying the electrode and guiding device of Ishikawa, the combination would allow for a seal to be formed between the outlet and the guiding device when the electrode/guiding device are in a retracted position.

Regarding claim 19, Cosmescu fails to disclose any specifics regarding the guiding device. Ishikawa discloses that the guiding device is comprised of a ceramic (see paragraph [0023]). In light of the combination provided in claim 1 above, it would have been obvious to supply the guiding device of the material specified by Ishikawa to provide for the above mentioned advantages.

Regarding claim 20, Cosmescu discloses a tube (tube **152**), an electrode disposed substantially coaxially with the tube (electrode **112**) and configured to generate high-frequency current wherein the distal end of the electrode projects outward of the tube (see at least figure 5). Cosmescu fails to disclose the specifics of the guiding device as claimed. Ishikawa discloses an argon plasma coagulating probe assembly (see at least figures 1-5) comprising a tube (probe **3** with insertion portion **9** formed of resin tube **15**), an electrode disposed substantially coaxially with the tube and configured to generate a high-frequency current (knife **13** connected to a source of energy as in paragraph [0012]), wherein a distal end of the electrode projects outward through an outlet of the tube (see figure 2 and 3 showing knife **11** extending out of the device through through-hole **47**). Ishikawa further discloses a guiding device disposed at the distal end of the electrode (insulating part **12**), wherein the guiding device is configured for guiding an inert gas stream delivered from the outlet of the tube (through-hole **47** with an inactive gas as disclosed in at least paragraph [0009] and see paragraph [0003] discussing ionizing inert gas,

paragraph [0051] discussing sprinkling hemostasis and paragraph [0053] discussing forming plasma), wherein a cross-section of at lest a portion of the guiding device is at least a size of the outlet in order to divert the inert gas stream substantially radially with respect to the outer of the gas-delivering device (as in figure 7, the plasma extends into the space radially outward with respect to the through hole **47** with the relative sizes of the part **12** in relation to the through-hole **47** as exhibited in figures 3 and 7 with the part **12** having a larger cross-section at its widest point than the widest portion of through-hole **47**), wherein the guiding device is comprised of an electrically insulating and thermally stable material (see at least paragraph [0023]) and is configured to have a concave configuration on a side thereof that faces the outlet (with respect to the embodiment in figure 15 that the guiding device (insulation part **12**) has a concave configuration on a side thereof that faces the outlet due to the shape of the transition between projection **40** and the remainder of part **12** having a concave-like configuration facing towards the through hole **47**) and is further configured to prevent mechanical damage if the guiding device touches the tissue (see the rounded shape of part **12** in at least figures 2 and 3), and wherein said electrode is movable relative to said outlet (see paragraph [0026] disclosing the movement/projection of the knife **11**) such that when said electrode is moved into a retracted position said guiding device closes said outlet in a substantially leakproof manner (see the relative diameter of part **12** in relation to through hole **47**, with respect to figure 15, paragraph [0047] discloses that the part **40** is greater in diameter than **47** thereby rendering **12** greater in diameter than **47** and with such a relation, when knife **11** and part **12** are retracted, a seal would be formed between **12** and the through hole **47**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the electrode (knife part

13) containing the guiding device (insulation part **12**) of Ishikawa in combination with the device of Cosmescu in order to have a combined device which can effectively cut, coagulate and supply plasma to a target tissue site. Both Cosmescu and Ishikawa are concerned with the direct contact and cutting/coagulation of tissue by the electrode as well as providing an argon plasma enhanced effect to treat a target site. Ishikawa provides an improvement to the device of Cosmescu by supplying the guide element, which as disclosed by Ishikawa, prevents the sticking of the electrode at a target area thereby reducing the unintentional bleeding (see paragraph [0007]) and ensures that plasma can still be created at that target site thereby allowing the continued treatment at the target site.

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa (JP 2002-301088 A) as applied to claim 9 above, and further in view of LaFontaine et al (US Pat. No. 5,902,328).

Regarding claim 14, Ishikawa discloses with respect to the embodiment in figure 15 that the guiding device (insulation part **12**) has a concave configuration on a side thereof that faces the outlet (the shape of the transition between projection **40** and the remainder of part **12** having a concave-like configuration facing towards the through hole **47**) and that the part **12** has a rounded, spherical shape. Ishikawa fails to specifically show or recite a flattened surface at a surface facing away. LaFontaine discloses a similar guiding device (deflecting body **100**) which redirects the flow of the fluid through a supply tube. LaFontaine further shows that the deflecting body **100** has a concave surface at a surface facing the outlet of the gas-delivery device and a flattened surface at a surface facing away from the outlet of the gas-delivering device wherein a transitional area between the concave surface and the flattened surface has a rounded contour

(see figure 7; it is noted that the face of **100** which faces away from the outlet of LaFontaine is seen by the Examiner, due in part to its reduced curvature with respect to the edges of **100** as being flattened with respect to those parts). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the shape of the guiding device of LaFontaine to the guiding device of Ishikawa to provide for a guiding device which can cause a reduced amount of mechanical damage due to the flattened surface. It is further noted that Applicant has failed to set forth any criticality or unexpected results which would render the provision of such a shape as a non-obvious variant.

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cosmescu et al (US Pat. No. 6,149,648) in view of Ishikawa (JP 2002-301088 A) and further in view of LaFontaine et al (US Pat. No. 5,902,328).

Regarding claim 14, Cosmescu fails to disclose any specifics regarding the guiding device. Ishikawa discloses with respect to the embodiment in figure 15 that the guiding device (insulation part **12**) has a concave configuration on a side thereof that faces the outlet (the shape of the transition between projection **40** and the remainder of part **12** having a concave-like configuration facing towards the through hole **47**) and that the part **12** has a rounded, spherical shape. Ishikawa fails to specifically show or recite a flattened surface at a surface facing away. LaFontaine discloses a similar guiding device (deflecting body **100**) which redirects the flow of the fluid through a supply tube. LaFontaine further shows that the deflecting body **100** has a concave surface at a surface facing the outlet of the gas-delivery device and a flattened surface at a surface facing away from the outlet of the gas-delivering device wherein a transitional area between the concave surface and the flattened surface has a rounded contour (see figure 7; it is

noted that the face of **100** which faces away from the outlet of LaFontaine is seen by the Examiner, due in part to its reduced curvature with respect to the edges of **100** as being flattened with respect to those parts). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the shape of the guiding device of LaFontaine to the guiding device of Ishikawa to provide for a guiding device which can cause a reduced amount of mechanical damage due to the flattened surface. It is further noted that Applicant has failed to set forth any criticality or unexpected results which would render the provision of such a shape as a non-obvious variant.

Response to Arguments

11. Applicant's arguments filed January 25th, 2011 have been fully considered but they are not persuasive.

Applicant has summarized the subject matter including the newly added limitations to claims 1, 9 and 20 on pages 6 and 7 of the Remarks. With respect to the rejection of claims 1, 3, 6-9, 12-13, 15, 17 and 19-21 under 35 U.S.C. 102(b) as being anticipated by Ishikawa et al, the Examiner respectfully disagrees with Applicant's reasoning set forth on page 8 of the Remarks. Therein, Applicant alleges that Ishikawa fails to disclose a guiding device as claimed and that the spherical part **12** of Ishikawa "is not, in fact, a guiding device for directing plasma, but instead a positioning aid for the instrument." Applicant also alleges on page 8 that the insulating part **12** of Ishikawa is smaller than the opening.

The Examiner has relied upon the through-hole **47** of Ishikawa throughout the rejections as the outlet of the gas-delivering device. As can be seen in at least figures 3 and 7 of Ishikawa, the spherical part **12** is displayed as having a greater major diameter than that of the wire **11** and

the through-hole **47** with paragraph [0027] readily giving the relative sizes between various portions of the device of Ishikawa. While Applicant has alleged that the part **12** of Ishikawa is smaller than the outer, Applicant has failed to recite in the arguments which portion of the device of Ishikawa is being taken as the outlet. While there are portions of the device of Ishikawa which may have a greater cross-section area at a point than that the part **12**, Applicant has not specifically addressed the relationship between the part **12** and through-hole **47** which the Examiner has relied upon in this action as well as the October 25th, 2010 final action.

It is also noted that with respect to figure 7 of Ishikawa, it can be readily seen that the plasma from the through-hole **47** is diverted "substantially radial" to the through-hole **47** and that such a diversion is provided at least by the part **12** being within the flow path of the plasma exiting the through-hole **47**. While the part **12** of Ishikawa may be described in paragraph [0042] of the machine translation as aiding in the positioning (by providing a moderate detachment between the probe and the membrane), it can readily be appreciated that the part **12**, in light of the function described above with respect to figure 7, is functioning as a guiding device as well.

Therefore, it is remains the Examiner's position that Ishikawa anticipates each of claims 1, 3, 6-9, 12-13, 15, 17 and 19-21 and that the above proffered rejections are tenable. Regarding newly added claim 22, the subject matter has been addressed in the rejections above.

With respect to the remarks directed towards the rejection of claims 1, 3, 6-9, 12, 13, 15, 17, and 19-21 under 35 U.S.C. 103(a) as being unpatentable over Cosmescu (US 6,149,648) in view of Ishikawa and the rejection of claim 14 under 35 U.S.C. 103(a) as being unpatentable over Ishikawa in view of LaFontaine (US 5,902,328), it is noted that Applicant's arguments are directed towards the alleged deficiencies of Ishikawa discussed on page 8 of the Remarks. Since

such deficiencies have been addressed above by the Examiner, it is the Examiner's position that the above remarks are fully responsive to Applicant's arguments on page 9. As such, the Examiner believes that the proffered rejection of claims 1, 3, 6-9, 12, 13, 15, 17, and 19-22 under 35 U.S.C. 103(a) as being unpatentable over Cosmescu (US 6,149,648) in view of Ishikawa and the rejection of claim 14 under 35 U.S.C. 103(a) as being unpatentable over Ishikawa in view of LaFontaine (US 5,902,328) are tenable.

Applicant is invited to contact the Examiner if any clarification or discussion of the above grounds of rejection is needed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald J. Hupczey/
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit 3739

RJH